



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/522,918

08/22/2005

Werner Bieberschulte

4358-16

4213

23117

7590

03/01/2010

NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER

BASQUILL, SEAN M

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

03/01/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Art Unit: 1612

DETAILED ACTION

Applicants are advised, in future correspondence with the office, to reflect the change of examiners from SARA CLARK to SEAN BASQUILL.

Status of the Claims

1. Claims 1 and 10-12 have been amended, and new claim 39 entered. Claims 15-38 remain withdrawn as directed to a nonelected invention. Claims 1-14 and 39 are presented for examination.

Previous Rejections

2. Applicants' arguments, filed 11 September 2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Terminal Disclaimer

3. The terminal disclaimer filed on 30 November 2009 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patents 5,563,140 and 6,573,265 has been reviewed and is NOT accepted.

It does not include a recitation that any patent granted shall be enforceable only for and during such period that said patent is commonly owned with the application(s) or patent(s) which formed the basis for the double patenting rejection. See 37 CFR 1.321(c)(3).

Art Unit: 1612

Claim Rejections - 35 USC § 112 Second Paragraph

4. While the examiner has withdrawn the previous rejections applied under 35 U.S.C. 112, second paragraph, addressing a matter of claim interpretation is appropriate at this time.

Applicants claims are directed to a “pharmaceutical formulation,” and while particular uses to which the formulation may subsequently be put follow such descriptive language (such as “for trans-tympanic or intra-transtypmanic administration,” which the examiner incidentally would consider language reciting largely equivalent actions, as both trans-tympanic and intratranstympanic administration of a composition is designed to permit the composition, and more pointedly the active agents contained therein, to cross the tympanic membrane; one method simply takes advantage of the presence of a tympanostomy tube), such language merely recites an intended use of the composition as claimed. *See* MPEP 2111.02(II) (indicating claim preambles which state the intended use of a claimed invention, rather than setting forth any distinct definition or limitation of the invention claimed, are not considered a limitation of the claim and are of no significance to the claims’ construction). As such, the phrases “for trans-tympanic or intra-transtypmanic administration” are immaterial to the examiner’s construction of the claim and search for art relevant thereto.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Art Unit: 1612

5. Claims 1-10 and 12 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,563,140 ("Ehrenberger"), in view of U.S. Patent 6,093,417 ("Petrus"), as put forth in paragraph 8 of the office action mailed 11 May 2009.

Applicants' arguments have been fully considered and are deemed unpersuasive. While Ehrenberger may direct particular embodiments of the invention described therein to the intravenous administration of quinoxaline-2-one compounds, the totality of the disclosure is not so limited when considered by one possessing ordinary skill in the art. Indeed, the disclosure of Ehrenberger particularly indicates only that "applications of these pharmaceuticals could be the treatment of glutamate-induced and glutamate-receptor-mediated neurotoxic dysfunctions such as functional disturbances of the inner ear, like tinnitus and impaired hearing." (C.2, L.57-60). This disclosure provides sufficient teaching to suggest to the skilled artisan that local administration of quinoxaline-2-one compounds may be advantageously used to treat functional disturbances of the inner ear, as *inter alia* Petrus clearly indicates that the local otic application of therapeutic drugs advantageously delivers active agents in close proximity to the target tissues. (C.3, L.41-52).

Applicants have, in essence, attempted to impose on the examiner a requirement that legally does not exist; namely that the prior art relied upon by the examiner specifically disclose teachings relevant to addressing the problems that the applicants' invention is directed to addressing. Such a rigid requirement is incompatible with the legal analysis of obviousness binding on the examiner. *See KSR International Co. v. Teleflex, Inc.*, 82 USPQ2d 1385, 1397 (U.S. 2007) (indicating that it is error to assume that a person of ordinary skill would be led only to those elements of prior art designed to solve the same problem). Stated properly, the examiner

Art Unit: 1612

bears the burden simply to articulate reasoning with some rational underpinning to support their legal conclusion of obviousness. (*Id. at* 1396). Neither is the examiner bound to the express language nor precise teachings of the prior art, as they are entitled to take account of the inferences and creative steps that a person of ordinary skill in the art would employ. (*Id.*) Within such a framework, it must be remembered that patents and prior art are relevant for all that they expressly contain and reasonably suggest to the skilled artisan. *See* MPEP 2123 (indicating art is relevant for all that it contains, not simply the particular problems with which they may be concerned). Given this understanding, the skilled artisan would clearly have reason to extend the utility of the permeation-enhanced otic compositions of Petrus beyond the narrow antiinflammatory and antiinfective uses particularly described; the disclosure repeatedly addresses the improved delivery to the cochlea of "active agents," not simply "antiinflammamtory agents," or "antibiotic agents" which constitute the preferred embodiments of the Petrus invention.

In addition, the examiner considers the purported "surprising and advantageous" properties of the composition claimed to be neither surprising nor unexpected, as the advantages disclosed therein can be found throughout the disclosure of Petrus. Applicants have, in essence, dubbed surprising that which is well-known within the otic arts.

6. Claims 1-14 stand and Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ehrenberger as modified by Petrus as applied to claims 1-10 and 12 above, and further in view of U.S. Patent 5,446,070 ("Mantelle") as put forth in paragraph 8 of the office action mailed 11 May 2009.

Art Unit: 1612

Applicants' arguments have been fully considered and are deemed unpersuasive for the reasons put forth above.

Double Patenting

7. Claims 1-14 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3, 7, and 9 of U.S. Patent No. 5,563,140 in view of Mantelle and Petrus as put forth in the previous action.

This rejection is maintained since applicant has (effectively) not responded to the rejection in a substantive manner. See 37 CFR § 1.111(b) and MPEP § 714.02.

8. Claims 1-14 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 3, 7, and 10 of U.S. Patent No. 6,573,265 in view of Mantelle and Petrus as put forth in the previous action.

This rejection is maintained since applicant has (effectively) not responded to the rejection in a substantive manner. See 37 CFR § 1.111(b) and MPEP § 714.02.

Conclusion

No Claims are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

Art Unit: 1612

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean Basquill whose telephone number is (571) 270-5862. The examiner can normally be reached on Monday through Thursday, between 8AM and 6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sean Basquill

Application/Control Number: 10/522,918

Page 8

Art Unit: 1612

Art Unit 1612

/JEFFREY S. LUNDGREN/

Primary Examiner, Art Unit 1639